

**Department of Labor and Industries
Office of the Medical Director**

**Health Technology Assessment
Extracorporeal Shockwave Therapy for the Treatment of
Musculoskeletal Disorders**

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Part 1. ESWT for the Treatment of Musculoskeletal Disorders

Extracorporeal shockwave therapy (ESWT) may initiate the following processes:

- structural changes on tissue
- stimulation of bone growth
- stimulation of the regenerative process in tissue
- structural changes in calcium deposits followed by reabsorption of the calcium by the body

Shockwaves are characterized by high positive pressure, a rise time lower than 10 ns, and a tensile wave. The positive pressure and the short rise time cause the direct shockwave effect. The tensile wave creates the indirect shockwave effect by affecting cavitation.

Interfaces between two materials with different acoustic impedance influence the direct shockwave effect. Reflection, refraction at the interface, and damping inside the material lead to energy loss of the shockwave. The fast pressure transition of shockwaves causes high tension at the interfaces. Depending on material plasticity, the structure of the material may crack.

The tensile part of a shockwave corresponds to the creation and growth of cavitation bubbles. The interaction between shockwaves and gas bubbles attached to a surface may result in the creation of holes on the surface. Bubble collapse also leads to further generation of shockwaves.

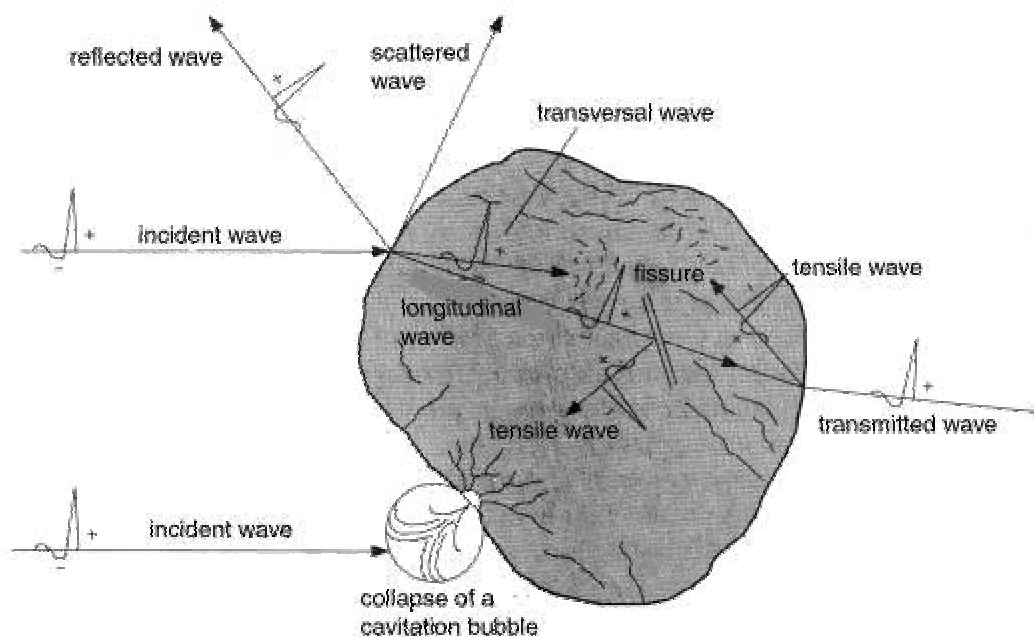


Fig. 1: Combination of direct and indirect shockwave effect to disintegrate a kidney stone.

The first ESWT treatments 20 years ago used ESWT in urology to disintegrate kidney stones. Researchers suggest that a combination of direct and indirect shockwave effects disintegrate the kidney stones. (Fig. 1)

Part 1. ESWT for the Treatment of Musculoskeletal Disorders

Although the precise mechanism of action for pain relief, bone growth stimulation, and other indications remains unknown, researchers have suggested a range of theories. One explanation suggests that the mechanical tissue disruption caused by ESWT may facilitate the neovascularization process, thereby stimulating pain relief. (Wheelock 2003) Another theory hypothesizes that shockwaves have a dose-dependent analgesic effect and relieve pain by hyperstimulation analgesia. (Crowther 2002) Finally, animal and histological investigations may show that shockwaves stimulate fracture healing by stimulating osteoblast activation.

Temporal and spatial distributions of shockwave pressure determine energy flux density (EFD) and pulse energy. EFD describes the maximum amount of acoustical energy transmitted through an area of 1 mm^2 per pulse. A shockwave with a focal EFD less than 0.1 mJ/mm^2 is considered low-energy whereas a shockwave with EFD greater than 0.2 mJ/mm^2 is considered high-energy. (Loew 1999) The total pulse energy describes the total acoustical energy per released shockwave.

The three types of generators that provide ESWT are electrohydraulic, electromagnetic, and piezoelectric generators.

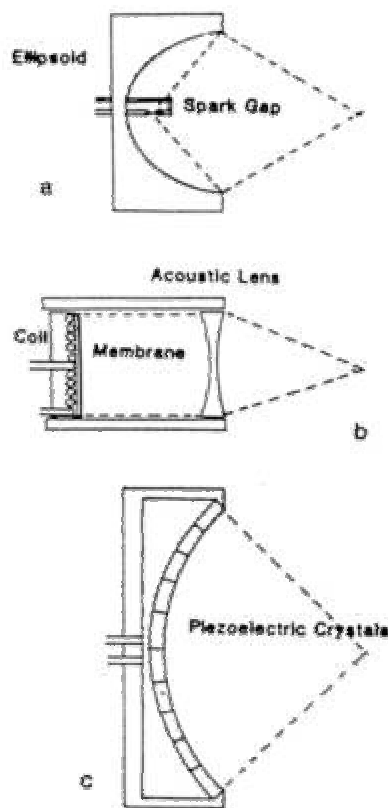


Fig. 2a, 2b, 2c: Principles of shockwave generation. a. electrohydraulic, b. electromagnetic, c. piezoelectric.

The electrohydraulic generator uses as a point source an electrode placed in the focal point F1 of a semi-ellipsoid reflector. A high voltage at the tips of the electrode generates an electrical spark

to release a shockwave. The metal ellipsoid reflects the spherical shockwaves into the second focal point F2, which is adjusted to the patient's body. (Fig. 2a)

Electromagnetic generators release a high current pulse through an electromagnetic coil to generate a varying magnetic field, which induces a current in an opposing metal membrane. The electromagnetic forces accelerate the metal membrane away from the coil creating a slow, low-pressure acoustical pulse. An acoustical lens defines the focal point and focuses the wave. Another construction uses the high current pulse to form a cylindrical pressure wave, which is focused by a hyperbolic metal reflector. (Fig. 2b)

The third generator forms acoustical waves using the piezoelectric effect. Switching a high voltage pulse to piezoelectric crystals mounted to a spherical surface causes the crystals to contract and expand. As a result, the crystals generate a self-focusing, low-pressure pulse. (Fig. 2c)

Researchers have examined the pressure distribution in the focal region of an electrohydraulic system (Dornier HM3) compared to an electromagnetic system (Siemens Lithostar Plus). Electrohydraulic devices generate shockwaves in a large focus volume and utilize the direct shockwave effect. In contrast, electromagnetic devices utilize the indirect shockwave effect by generating waves in the focus center and in a small area around the center. As a result, electrohydraulic shockwaves may show higher efficiency in application in medicine. (Thiel Undated)

According to the European Society for Musculoskeletal Shockwave Therapy, the following contraindications exclude a patient from receiving ESWT (European 1998):

- acute infection of soft tissue/bone
- malignancy
- epiphysis in the focus
- blood coagulation disorders
- pregnancy
- pacemakers
- lung tissue, brain, spinal marrow, or larger nerves (neurocranium, spinal column, ribs) in the focus

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Part 2. ESWT for the Treatment of Plantar Fasciitis

Plantar fasciitis most commonly affects middle-aged men and women. Other risk factors include obesity and spending prolonged periods standing or walking, particularly on hard floors. Over 80% of those who present for medical attention for plantar heel pain experience resolution within 12 months of symptom onset. (Buchbinder 2002)

I. FDA Status

The FDA granted a Pre-Market Approval to HealthTronics for their OssaTron system in October 2000. The system received a classification of “Generator, Shockwave, (For Pain Relief)”. OssaTron uses high-energy electrohydraulic technology to generate shockwaves for the treatment of proximal plantar fasciitis that has failed to respond to conservative treatment. Chronic proximal plantar fasciitis is defined as “pain in the area of the insertion of the plantar fascia on the medial calcaneal tuberosity that has persisted for more than six months.” (FDA 2000)

In January 2002, the FDA granted a Pre-Market approval to Dornier for its EPOS Ultra Device. The EPOS Ultra treats plantar fasciitis, which is defined as the “traction degeneration of the plantar fascial band at its origin on the medial tubercle of the calcaneus.” The low-energy Dornier does not require anesthesia when used for plantar fasciitis. (FDA 2001)

II. Evidence

The majority of the studies excluded subjects due to infection, pregnancy, osteoarthritis or rheumatoid arthritis, neurologic abnormality, nerve entrapment, or malignancy.

A. Case Series and Non-Randomized Studies of ESWT for Plantar Fasciitis

1. Maier conducted a study examining the effect of ESWT on plantar fasciitis and correlations between MRI and outcome. Following clinical, radiological, and MRI exams, subjects underwent ESWT. A 100-point VAS measured pain at 6 and 36 months. The Roles and Maudsley score defined clinical performance.

Researchers evaluated the MRI for maximum thickness and signal pattern of the plantar aponeurosis and presence of bone marrow edema of the calcaneus.

The Storz Minilith, Dornier Compact, or Dornier Epos Ultra administered the ESWT. Patients received 2000 pulses (EFD 0.15 mJ/mm²) in weekly intervals at 3 to 5 sessions.

Study Population: The study included patients with pain at the insertion zone of the plantar fascia at the medial aspect of the calcaneus of more than 6 months. Radiological evidence proved plantar calcaneal spurs. Patients also failed conservative treatment over a 6-month period. Patients were excluded due to

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ankylosing spondylitis, Reiter's syndrome, or previous surgery or ESWT to the heel. Researchers also excluded patients with metal implants.

The study included 43 patients (48 heels).

Results: The average VAS score decreased from 74.46 to 25.40 after ESWT at average 19.3-month follow-up. The average Roles and Maudsley score equaled 1.938. The researchers did not detect statistical differences between males and females or between subjects who received 3 compared to 5 treatments.

MRI signs for bone marrow edema correlated significantly with patient Roles and Maudsley scores. Edema classified as linear or diffuse had a positive predictive value of 0.94, sensitivity of 0.89, and specificity of 0.8 with respect to satisfactory clinical outcome.

Conclusion: The study indicates that the presence of calcaneal bone marrow edema on pre-therapeutic MRI is a good predictive variable for satisfactory clinical outcome.

2. Chen prospectively examined the effectiveness of shockwave therapy in patients with painful heel syndrome. A 100-point scoring system evaluated patient pain and function. A 10-point VAS measured pain intensity. Follow-up occurred at 6, 12, and 24 weeks.

The researchers administered 1000 impulses at 14 kV (EFD 0.18 mJ/mm²) with the HealthTronic's OssaTron.

Study Population: The study included patients with refractory heel pain syndrome with inadequate response to treatment for at least 6 months. Patients stopped other therapies 2 weeks prior to ESWT.

The 80 patients had an average age of 48 years.

Results: Six patients were lost to follow-up. The researchers suggest that the effect of shockwaves continues to improve from 3 to 6 months.

Number and Percent of Subjects by Outcome and Follow-up

| | Pre-Treatment | 6 weeks | 12 weeks | 3 months | 6 months |
|----------------------------|---------------|---------------|---------------|---------------|---------------|
| Number of Subjects (Heels) | 74 (80 heels) | 64 (68 heels) | 64 (68 heels) | 52 (54 heels) | 52 (54 heels) |
| Number (%) of Subjects | | | | | |
| No Complaints | | 6 (8.8%) | 13 (19.1%) | 11 (20.3%) | 31 (57.4%) |
| Significantly Better | | 24 (35.3%) | 37 (54.4%) | 29 (53.7%) | 15 (27.8%) |
| Slightly Better | | 32 (47.1%) | 12 (17.7%) | 9 (16.7%) | 8 (14.8%) |
| Unchanged | | 6 (8.8%) | 6 (8.8%) | 5 (9.3%) | |

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Average Assessment Scores by Follow-up

| Assessment | Pre-Treatment | 6 weeks | 12 weeks | 3 months | 6 months |
|----------------|---------------|---------|----------|----------|----------|
| Pain Score | 29.3 | 51.3 | 59.7 | 60.3 | 65.2 |
| Function Score | 15.2 | 22.9 | 25.6 | 26.0 | 28.1 |
| VAS Score | 2.9 | 6.0 | 7.2 | 7.3 | 8.7 |

Conclusion: The authors conclude that ESWT is safe and effective in the treatment of patients with painful heel syndrome.

3. Wang reported an update of a case series study examining the effect of ESWT on plantar fasciitis.¹ (Wang 2002)

The HealthTronic's OssaTron administered 1000 impulses at 14 kV (EFD 0.18 mJ/mm²). The outcome of pain intensity was measured on a 10-point VAS with 10 as no pain. The researchers also used a 70-point clinical pain scale and a 30-point function scale.

Follow-up occurred at 6 weeks as well as 3, 6, and 12 months after therapy.

Study Population: The study included patients with refractory painful heel spurs that failed to respond to conservative treatment for at least 6 months. Additional exclusion criteria included diabetes, vascular disease, or metabolic diseases.

The study's 79 patients (85 heels) had an average age of 47 years and an average duration of symptoms of 9.8 months.

¹ Wang's initial short-term study followed patients for 6, 12, and 24 weeks after treatment. (Wang 2000)

Number of Subjects and Average Assessment Scores at Follow-up

| | | 6 week | 12 week |
|---|-------------|----------|----------|
| Subject Number at Follow-up | | 58 | 41 |
| VAS score | Before ESWT | 2.38 | 2.49 |
| | After ESWT | 5.76 | 7.63 |
| Total Pain score | Before ESWT | 23.83 | 25.93 |
| | After ESWT | 48.97 | 61.2 |
| Function score | Before ESWT | 14.81 | 14.98 |
| | After ESWT | 22.86 | 26.68 |
| Subject Number (%) Showing Greater than 50% Improvement | | 35 (61%) | 36 (88%) |

For the 41 subjects who completed 12-week follow-up, the data showed that the effect of ESWT on painful heels continued between 6 and 12 weeks. Of the 7 who completed 24-week follow-up, 6 showed greater than 50% improvement. The authors conclude that treatment of painful heels with ESWT produced a high rate of success in pain relief and functional restoration with negligible complications.

Part 2. ESWT for the Treatment of Plantar Fasciitis

Results: Sixteen patients received a second treatment 30 to 45 days after the initial treatment due to inadequate response. Five patients underwent three treatments.

Number and Percent of Heels by Number of Treatments and Follow-up

| | One Treatment | | Two Treatments | |
|--|------------------|---------------|------------------|---------------|
| | Before Treatment | 12-Months | Before Treatment | 12-Months |
| Number of Heels | 60 | 60 | 19 | 19 |
| Number (%) of Complaint Free Heels | | 49 (81.7%) | | 12 (63.2%) |
| Number (%) of Significantly Better Heels | | 9 (15.0%) | | 4 (21.1%) |

Average Assessment Scores by Number of Treatments and Follow-up

| | One Treatment | | Two Treatments | |
|----------------------|------------------|-----------|------------------|-----------|
| | Before Treatment | 12-Months | Before Treatment | 12-Months |
| Total Pain Score | 25.4 | 67.7 | 38.8 | 67.1 |
| Total Function Score | 14.1 | 29.0 | 16.7 | 28.5 |

Conclusion: The authors conclude that ESWT is a safe and effective modality in the treatment of plantar fasciitis, and the effects of therapy are long lasting.

B. Trials of ESWT for Plantar Fasciitis with Control or Comparison Groups

1. The single-blind, randomized pilot study used the Siemens Osteostar to administer 3 ESWT treatments at weekly intervals. Patients in the active treatment group received 1000 impulses, .06 mJ/mm², around the heel spur. (Rompe 1996)

Follow-up at 3, 6, 12, and 24 weeks examined

1. pain using a 100-point VAS
2. pain-free plantar pressure measured and registered in kg
3. walking ability without the need to rest
4. pain compared to pre-treatment

Study Population: Researchers excluded patients due to dysfunction in the knee or ankle, spondylitis, or Reiter's syndrome.

After 6 subjects were lost to follow-up, 30 patients with an average pain history of 18 months remained at follow-up.

The 15 subjects in the active ESWT group had an average age of 47 years and an average duration of pain of 16 months (range 12 to 36 months). The 15 subjects in

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the placebo group had an average age of 51 years and an average duration of pain of 22 months (range 12 to 38 months).

Results:

% Decrease in Score Compared to Baseline

| | | 3 weeks | 6 weeks |
|---------------------|---------|---------|---------|
| Night Pain | Active | 58.2 | 57.4 |
| | Placebo | 13.6 | 8.1 |
| Resting Pain | Active | 75.0 | 79.6 |
| | Placebo | 36.6 | 33.8 |
| Local Pressure Pain | Active | 66.7 | 67.2 |
| | Placebo | 8.5 | 7.5 |

Number of Subjects by Category at 6 weeks

| | Active | Placebo |
|--------------------------|--------|---------|
| Total Number of subjects | 15 | 15 |
| Pain Free | 2 | 0 |
| Improved | 8 | 4 |
| Unchanged | 5 | 11 |

Walking ability increased 171.4 % at 3 weeks and 178.6% at 6 weeks for the treatment group compared to 0% and 4.8% for the placebo group.

2. Ogden's journal article describes the Pre-Market Approval study that HealthTronics submitted to the FDA. The study may also include the study population from Alvarez's observational study that *Foot and Ankle International* published in March 2002.² (Ogden 2001)

² Alvarez conducted an observational study using a VAS, which measured patient response to pressure as well as patient pain. Researchers defined success as a 50% reduction in pain from baseline after 2 treatments. Follow-up occurred at 6 weeks, 3 months, 6 months, and 1 year. The study implemented intention to treat. (Alvarez 2002)

The HealthTronics OssaTron provided 1000 shocks to each heel pain region. Settings advanced every 10 shocks to a maximum of 16 kV at a frequency of 2 hertz.

Study Population: The study included patients whose pain did not respond to 2 forms of non-surgical treatment in the previous 6 months. The 20 subjects (median age 51 years) had symptoms that lasted an average of 22 months.

Results: On the investigator assessment at 3 months, the 18 patients characterized as successful averaged 85.7% improvement on the VAS. At 12 months, the subjects had a mean VAS improvement of 95.8%. The 15 successful subjects at 3 months on the self-assessment averaged 63.8% improvement on the VAS. The 17 patients who met success at 12 months experienced a mean improvement of 70.8%.

Number of Subjects by Assessment and Follow-up

| | | 3 month | 12 month |
|-------------------------------------|--|-----------|-----------|
| Investigator Assessment | | | |
| Number meeting criterion of success | | 18 (90%) | 20 (100%) |
| Self-Assessment | | | |
| Number meeting criterion of success | | 15 (75%) | 17 (85%) |
| Improved walking in the morning | | 20 (100%) | 18 (90%) |

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One blinded evaluator and one non-blinded investigator performed the procedure.

Each subject received a total of 1500 shocks delivered at a power setting of 18kV. Treatment time averaged 17 minutes.

Researchers defined success as meeting the 4 following criteria at 12-week follow-up.

1. minimum 50% improvement over baseline and maximum score of 4 on the VAS on the investigator assessment
2. minimum 50% improvement over baseline and maximum score of 4 on the VAS on the self-assessment
3. improvement of 1 point or maintenance of baseline score of 0 or 1 on 5-point scale for walking ability
4. no administration of pain medications for heel pain at 12-week follow-up

Study Population: Researchers included subjects in the study if they had proximal plantar fasciitis persisting for at least 6 months. According to investigator assessment, patient pain originated at the plantar fascia on the medial calcaneal tuberosity and received a score of 5 cm or above on a 10 cm VAS. According to self-assessment, subject pain during the first five minutes of walking in the morning scored 5 cm or above on a 10 cm VAS. Subjects must also have failed 2 courses of non-invasive treatment and a course of pharmacological treatment.

Subjects were excluded due to heel pain from other causes, osteoporosis, metabolic disorders, Paget's disease, osteomyelitis, or fracture.

Of the 314 subjects who enrolled in the study, 302 subjects completed study treatment. However, 26 of the 302 subjects withdrew, did not complete, or were lost to follow-up at 12-weeks. Therefore, 235 randomized and 41 nonrandomized subjects remained for inclusion in the report.

The average age of the subjects was 49.6 years (range 20 to 69 years). The symptom duration for the 119 subjects in the active treatment group averaged 968 days compared to 1078 days for the 116 placebo subjects. Non-randomized subjects experienced symptoms for an average of 943 days (range 4.6 months to 10 years).

Results:

Average VAS Scores according to Treatment Group and Assessment

| | Active | Placebo |
|-------------------------|--------|---------|
| Investigator Assessment | | |
| VAS before treatment | 7.68 | 7.87 |
| VAS after treatment | 3.13 | 4.37 |
| Subject Self-Assessment | | |
| VAS before treatment | 8.02 | 8.2 |
| VAS after treatment | 3.48 | 4.2 |

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| | | |
|------------------------------|------|------|
| Distance walked without pain | | |
| VAS before treatment | 3.49 | 3.53 |
| VAS after treatment | 1.72 | 1.88 |

At baseline, 106 subjects (89.1%) in the active group were using pain medications. After receiving ESWT, 36 subjects (30.3%) continued to use medication at 12-week follow-up.

Of the 119 active treatment subjects followed to 12 weeks, 56 subjects (47.1%) met all 4 success criteria compared to 35 of the 116 placebo subjects (30.2%).

Researchers found a significant association between duration of symptoms and successful outcome. Subjects with a shorter duration of symptoms had higher response rates.

Researchers reported complications and adverse events for both the active and placebo groups. Thirty-eight complications occurred, including 25 in the active group and 13 in the placebo group. Four subjects from the treatment group and 4 subjects from the placebo group experienced post-treatment pain. Six subjects from the treatment group and 1 placebo subject experienced numbness and tingling. Two subjects who received active ESWT sustained midsubstance plantar fascia tears.

Conclusion: The pre-clinical and clinical data assure the safety and effectiveness of the HealthTronics OssaTron device when used in accordance with the device labeling.

2. Cosentino's single-blind trial randomized consecutive patients to 1 of 2 groups. Group 1 received 6 active treatments, once every 7-10 days, with an energy density varying from .03 to .4 mJ/mm². The 1200 shocks were administered at a frequency of 120 shocks/minute. Group 2 received 6 placebo treatments, once every 7-10 days, with an energy density of 0.0 mJ/mm². The study employed electrohydraulic shockwaves from the Orthima Direx Medical System. (Cosentino 2001)

Pain levels were measured on a 10-point VAS with 10 as maximum pain. An excellent rating indicated a VAS reduction of at least 50% while a good rating showed a 30% to 50% VAS reduction. Follow-up occurred at 1 and 3-months.

Study Population: The study included patients who had radiologically confirmed heel spurs and failed conservative treatment in the previous 6 months. The 60 patients had an average age of 55.6 years. Symptom duration averaged 8.6 months for the active treatment group and 8.2 months for the placebo group.

Results: The active group experienced significant decreases on the VAS at rest, after walking, on awakening, and after normal daily activity. Sonographic evaluation showed that 12 out of 30 (40%) patients had decreased enthesitis after 1 month.

Of the 30 placebo group subjects, 2 (7%) subjects showed an enthesitis reduction, 4 (13%) subjects worsened, and 24 (80%) subjects remained unchanged.

Conclusion: The authors conclude that ESWT effectively reduced painful symptoms and that patients maintained the reduction in pain over the following 3 months.

3. Rompe's prospective, randomized, observer-blinded pilot trial determined the presence of a dose-dependent effect of low-energy ESWT on recalcitrant heel pain. (Rompe 2002)

A blinded observer rated pain at 24-week and 5-year follow-up. A rating of excellent or good at follow-up determined success. Patients achieved excellent ratings if they experienced no pain, satisfaction with treatment outcomes, and unlimited walking without pain. A rating of good necessitated decreased symptoms, patient satisfaction with treatment outcomes, and the ability to walk for more than one hour without pain.

The study used the Siemens Osteostar to deliver ESWT to two groups. Group 1 received 3 applications of 1000 impulses of low-energy shockwaves (EFD .08 mJ/mm²). Group 2 received 3 applications of 10 impulses of low-energy shockwaves (EFD .08 mJ/mm²).

Study Population: Subjects met eligibility criteria if they experienced heel pain for more than 6 months and had failed conservative treatment at least 6 months before referral to the study. In addition, radiography showed a plantar heel spur in the area of the medial calcaneal tuberosity.

The study excluded subjects for knee or ankle dysfunction, ankylosing spondylitis, Reiter syndrome, or previous operation on the heel.

Of the study's 119 included subjects (average age 46 years), 112 subjects agreed to the randomization process. The high-dose group experienced pain for an average of 8 months while the low-dose group experienced pain for an average of 10 months.

The study excluded 13 patients based on exclusion criteria.

Results:

| Number (%) of Subjects by Assessment, Treatment Group, and Follow-up | | | | |
|--|-----------|----------|-----------|----------|
| | 6 months | | 5 years | |
| | High Dose | Low Dose | High Dose | Low Dose |
| Available for follow-up | 49 | 48 | 38 | 40 |
| Rating | | | | |
| excellent | 6 (12%) | 0 (0%) | 12 (32%) | 15 (38%) |
| good | 22 (45%) | 5 (10%) | 18 (47%) | 12 (30%) |
| Sought other treatment | 10 (20%) | 44 (92%) | 5 (13%) | 32 (80%) |

At 6 months, outcomes for the high dose group differed significantly compared to the low dose group. Twenty-five subjects from the high dose group and 0 subjects from the low dose group were able to walk without pain at 6 months. At 5-year follow-up, the success rate between the two groups was no longer statistically significant.

Conclusion: The pilot study revealed a dose-related effect of low-energy ESWT in patients with chronic plantar fasciitis. The authors also state that they cannot recommend ESWT as a first-line procedure for chronic heel pain.

4. Weil compared ESWT to percutaneous plantar fasciotomy (PPF) for the treatment of plantar fasciitis. (Weil 2002) Patients chose whether to pursue conservative care, ESWT with an electrohydraulic generator, or PPF.

A VAS measured patient's pain during ambulation. Follow-up occurred at 7 days, 6 weeks, and 3 months.

The energy intensity applied ranged from 17 to 21 kV with 1500 to 3000 pulses.

After treatment, all patients continued with their conservative care treatments, including orthoses, exercises, and NSAIDs.

Study Population: Subjects experienced heel pain for over 6 months and had not responded to 4 or more types of conservative treatments. Subjects were excluded from the study if they had heel surgery and pain with systemic comorbidities or nerve related symptoms.

The study included 94 patients with recalcitrant heel pain who had failed conservative treatment. After considering the options, 49 subjects chose to continue conservative care, 9 patients chose PPF, and 36 patients chose ESWT (40 feet).

Results: The researchers do not report the results of subjects who chose to continue conservative care. Eighty-three percent of the patients who chose PPF reported feeling satisfied with the surgery compared to 82% of the ESWT subjects. However, follow-up times between the two groups differed significantly.

For the ESWT subjects, the average pretreatment VAS equaled 7.9 compared to 4.2 at 3-month follow-up. At a mean follow-up of 8.4 months, 50% showed greater than 50% improvement on the VAS. Those who were satisfied with treatment had experienced pain for an average of 17.2 months compared to 32.9 months for those who were dissatisfied treatment. An average of 20.6 kV and 2506 pulses was used during the procedure.

One person experienced a transient rash that resolved after 6 weeks.

Conclusion: ESWT provides a safe and statistically reliable reduction of pain associated with plantar fasciitis.

5. Buchbinder conducted a double-blind, randomized, placebo-controlled trial to examine the effect of ESWT on plantar fasciitis.

Randomization occurred through stratification by treatment center in blocks of four. Patients received active or placebo treatment according to a computer generated random numbers list. (Buchbinder 2002)

The Dornier EPOS Ultra provided 3 treatments given at weekly intervals. The placebo group received 100 shockwaves per treatment at a frequency of 60 shocks per minute for a total dose of 6 mJ/mm². The experimental group received between 2000 and 2500 shockwaves per treatment with energy levels varying between .02 mJ/mm² and .33 mJ/mm². The treatment gradually increased to the highest tolerable level of pain for each participant. While the total dose for each person differed, the mean for the group equaled 1406.73 mJ/mm².

Follow-up at 6 weeks and 12 weeks examined 7 outcomes:

1. Overall, morning, and activity pain on a 100-point VAS with 0 as no pain
2. Walking ability without need to rest
3. Maryland Foot Score to assess disability
4. Problem Elicitation Technique – a patient preference disability measure
5. Short Form 36 Health Survey
6. Adverse events
7. Success of blinding

The overall pain score at 12-week follow-up acted as the primary endpoint for efficacy and sample size. A pilot study showed that a sample size of 60 patients per group would have 80% power to detect a difference of 13mm in pain level between the groups at 12-week follow-up.

The researchers did not allow any other therapies for the duration of the study and practiced intention to treat.

Study Population: Investigators included subjects who experienced heel pain over the plantar aspect for at least 6 weeks and had an ultrasound-confirmed lesion.

Exclusion criteria included wound or skin lesions, bleeding disorder, pacemaker, previous surgery to the heel, previous ESWT, anti-inflammatory medication in the previous 2 weeks, corticosteroid injection in the previous month, or oral glucocorticosteroids in the previous 6 weeks.

81 subjects were included in the ESWT treatment group, and 85 subjects were included in the placebo group. Investigators did not detect any differences in baseline characteristics between the two groups.

Results: Both the treatment and the placebo groups improved over time. At 6 and 12-week follow-up, the active group did not differ statistically in the measured outcomes from the placebo group. Participants in both groups improved with respect to pain by almost 20 mm (6 weeks) and 25 mm (12 weeks) with similar improvements in function. The results remained similar after adjusting for duration of symptoms, thickness of lesions, unilateral and bilateral symptoms, and total dose of ESWT.

Adverse events in both groups included pain (1 from each group), 1 burning sensation (placebo), and 1 bruising (active).

Nineteen subjects (24.4%) in the active group identified their group correctly compared to 29 subjects (36.2%) from the placebo group. This suggests a statistically significant amount of blinding beyond that expected by chance.

Conclusion: The researchers failed to find any evidence of benefit of ultrasound-guided ESWT over placebo for ultrasound-confirmed plantar fasciitis at 6 and 12-week follow-up.

C. Meta-evaluations of Studies on ESWT for Plantar Fasciitis

1. Boddeker biometrically evaluated trials published in English and German studying ESWT as a treatment for heel spur or plantar fasciitis. None of the 17 study designs fulfilled all of the biometrical criteria recommended for clinical trials. The only principle in all the studies was the use of a clinically relevant endpoint. The authors conclude that available data do not confirm or exclude the effectiveness of ESWT as a treatment for plantar fasciitis. (Boddeker 2001)
2. Ogden's corporate-sponsored review³ of plantar fasciitis revealed 20 publications and abstracted studies involving at least 1,601 patients. Of these studies, 8 studies fit the categorization of Type A to C studies representing 840 patients. Published Type A studies included 322 subjects. (Ogden 2002)

The authors state that the data from the studies support a positive response to ESWT with clinical response usually lasting at least one year. They conclude that high-energy shockwave impulses appear to be effective for bringing about patient relief with fewer treatments and in a greater percentage of patients than low-energy impulses.

3. Crawford et al reviewed randomized and quasi-randomized trials to identify and to evaluate the evidence for effectiveness of treating plantar heel pain. (Crawford 2002)

Two reviewers independently evaluated studies for inclusion, extracted data, and study quality, but were unable to identify poolable data.

Results: The review included 11 randomized trials involving 465 participants. Seven trials evaluated interventions against placebo or no treatment. All studies measured a reduction in heel pain as the primary outcome.

The included studies examined:

- topical corticosteroids, administered by iontophoresis in reducing pain
- injected corticosteroids
- low ESWT in reducing night, resting, and pressure pain in the short term

³ Because the authors do not pool data from the included studies, the article may be considered a review rather than a meta-analysis despite the article title.

Part 2. ESWT for the Treatment of Plantar Fasciitis

- dorsiflexion night splints in reducing chronic pain (longer than 6 months)
- therapeutic ultrasound
- low-intensity laser therapy
- electron generating devices
- insoles with magnetic foil

Although the effectiveness of corticosteroid injections has not been demonstrated against a placebo, limited evidence suggests their superiority over certain types of orthotics. Limited evidence also indicates that the use of night splints may benefit chronic plantar heel pain. There is limited evidence for the effectiveness of low energy ESWT in reducing pain.

No evidence supports the effectiveness of therapeutic ultrasound, low-intensity laser therapy, or exposure to an electron generating device or insoles with magnetic foil. No randomized trials evaluating orthotics devices, surgery, or radiotherapy against a control population have been identified.

Conclusion: The reviewers conclude that several interventions have treated heel pain, but few have undergone rigorous evaluation. They also indicate a need for well designed and conducted randomized controlled studies.

III. Costs

An orthopedic clinic in Seattle, WA intends to charge \$900 per low-energy treatment session. Each treatment requires use of a treatment room for one and a half hours including preparation and clean-up.

A recent request for a high-energy treatment charged the following:

| <u>Item</u> | <u>Code</u> | <u>Charge</u> |
|-------------------|-------------|---------------|
| Provider | 0020T | \$1500 |
| OssaTron Services | 0020T | \$4500 |
| Anesthesia | | \$300-\$500 |

A third provider has charged a total of \$7,485 under code 0020T.

IV. Department Issues

In 2002, the Department of Labor and Industries accepted 354 claims under the International Classification of Diseases code 728.71, plantar fasciitis.

Top 16 Treatments for Plantar Fasciitis Claims Paid by LNI, 2002

| Number of Paid Requests | CPT or HCPCS Code | Therapy |
|------------------------------------|------------------------------|---|
| 373 | 97140 | manual therapy techniques (mobilization, manipulation, manual traction) |
| 305 | 97035 | ultrasound stimulation |
| 296 | 97110 | therapeutic procedures to develop strength, endurance, ROM, flexibility |
| 188 | 97014 | electrical stimulation |
| | | therapeutic activities, use of dynamic activities to improve functional |
| 107 | 97530 | performance |
| | L3000, L3020, | |
| 80 | L3030 | foot inserts |
| | 73620, 73630, | |
| 75 | 73650 | radiologic exam |
| 61 | 97001, 97002 | PT |
| 47 | 20550 | injection, tendon sheath, ligament |
| 36 | 97022 | whirlpool |
| 31 | 97537 | community/work reintegration, self-care/home management |
| 23 | 29540 | ankle, foot strapping |
| 22 | 97113 | aquatic therapy |
| 21 | J8499 | oral prescription drug, NOS |
| 18 | 97124 | massage |
| 14 | J3301 | injection triamcinolone acetonide |

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Part 2. ESWT for the Treatment of Plantar Fasciitis

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Part 3. ESWT for the Treatment of Lateral Epicondylitis

The etiologic origin on lateral epicondylitis includes injury, mechanical imbalance, aging, and chemical, vascular, hormonal, and hereditary factors. Wang cites a Nirschl study of 1,213 patients with lateral epicondylitis, which found that 7.3% required surgery after failing conservative therapy. (Wang 2002)

I. FDA Status

In July 2002, the FDA granted Pre-Market Approval to Siemens for its SONOCUR Basic device. The device provides treatment for patients with symptoms of chronic lateral epicondylitis lasting more than 6 months and unresponsive to conservative treatment. The low-energy, electro-magnetic Sonocur treatment does not require anesthesia and can be administered in an office setting.

II. Evidence

The majority of the studies excluded subjects due to infection, pregnancy, arthritis, cardiac arrhythmia, neurological abnormality, or malignancy.

A. Case Series Studies of ESWT on Lateral Epicondylitis

1. Maier examined in a prospective case series whether magnetic resonance imaging (MRI) acted as a predictive parameter for clinical outcome. Patients with chronic lateral tennis elbow underwent MRI before ESWT. A 100-point VAS measured patient pain. Researchers compared data from the clinical exam before ESWT to data gathered at average 19-month follow-up. (Maier 2001)

MRI determined the presence or absence of signal intensity changes or contrast enhancement of the common extensor tendon.

The study used the Minilith SL1, Compact S, or the Epos Ultra to provide ESWT. Subjects underwent 3 or 5 single treatment sessions at weekly intervals. They received 2000 pulses with a frequency of 2 Hz for an EFD of .15 mJ/mm.

The Roles and Maudsley score categorized ESWT performance.

Grade 1: excellent – no pain, full movement and activity

Grade 2: good – occasional pain, full movement and activity

Grade 3: acceptable – some discomfort after prolonged activity

Grade 4: poor – pain limiting activity

Study Population: The study included 42 subjects with chronic lateral tennis elbow of more than 6 months and unsuccessful conservative therapy. Patients were excluded if they presented with radial tunnel syndrome, elbow instability, local bursitis, gout,

Part 3. ESWT for the Treatment of Lateral Epicondylitis

dysfunction of the ipsilateral shoulder joint, trauma, surgery, previous ESWT, metal implants, or injections into the elbow within 12 weeks before ESWT.

Results: The mean VAS score for female patients significantly decreased from 68.9 to 34.1. The mean VAS score for male patients significantly decreased from 66 to 17.6. Researchers detected significant differences between post-treatment scores for females compared to males.

Researchers also found a significant difference between female and male patients on T1-CM and T2. T1-CM and T2 showed significant differences when examining patients with Roles and Maudsley Scores of 1 or 2 compared to patients scoring 3 or 4. Researchers did not detect this difference in male subjects.

Using T2, the diagnosis area of increased signal intensity with tendon thickening of common extensor tendon had a positive predictive value of .6, a sensitivity of 1, and specificity of .42. using T1-CM, the diagnosis 'area of increased signal intensity with tendon thickening of common extensor tendon' had a positive predictive value of 0.67, a sensitivity of 1.00, and a specificity of 0.5.

Principal findings: At 19-month follow-up, 52% of female and 84% of male patients with lateral tennis elbow showed better clinical performance after ESWT than before treatment.

Males and females differed in signal intensity of common extension tendon cross-section and tendon thickening in T1 and T2 MRI scans of lateral tennis elbow. The study suggests that T2 and T1-CM MRI may predict satisfactory clinical outcome of ESWT for female patients.

2. Wang reported an update on a case series study examining the effect of ESWT on lateral epicondylitis.⁴ (Wang 2002)

⁴ Ko published in 2001 the results of short-term results from the case series.

| Number of Subjects and Average Assessment Scores at Follow-up | | | | |
|---|---------------------|------------|------------|------------|
| | Before Treatment | 6-week | 12-week | 6 months |
| Number of Patients | 53 | 47 | 35 | 25 |
| Pain Score | 16.7 | 25.3 | 30.1 | 34 |
| Function Score | 14.5 | 20.8 | 24.5 | 26.4 |
| Elbow Motion Score | 9.7 | 9.9 | 10 | 10 |
| Total Score | 41 | 64.4 | 77.6 | 87.8 |
| Number (%) of patients rated as: | | | | |
| Excellent | | 1 (2%) | 5 (13.2%) | 8 (30.8%) |
| Good | | 16 (34.7%) | 16 (44.7%) | 10 (42.3%) |
| Number (%) of patients with 50% improvement | | 26 (53.1%) | 23 (60.5%) | 18 (73.1%) |

Researchers found statistically significant improvement in function and pain when comparing 6 and 12-week results as well as when comparing 6-week and 6-month results. However, the early period from 6 weeks to 3 months showed a more dramatic magnitude of improvement. The researchers conclude that low-energy ESWT seems to be effective for lateral epicondylitis of the elbow in selected patients. (Ko 2001)

Part 3. ESWT for the Treatment of Lateral Epicondylitis

The researchers evaluated patients using a 100-point system that designated 40 points for pain, 30 points for function, 20 points for strength, and 10 points for range of motion. A 10-point VAS measured pain intensity with 0 set as severe pain.

Researchers defined an excellent result as no pain, full motion and activity. Subjects received good ratings if they experienced occasional soreness, good motion and activity. The average length of follow-up for the group was 17.4 months

The OssaTron orthotripter provided 1000 impulses of shockwaves at 14 kV (EFD 0.18 mJ/mm²).

Study Population: The study included subjects with lateral epicondylitis that did not respond to at least 6 months of conservative treatment. All patients discontinued other treatments, including non-steroidal anti-inflammatory drugs for 2 weeks before treatment.

Researchers treated 58 elbows with refractory lateral epicondylitis in 57 patients. Patient age averaged 46 years and the duration of their conditions averaged 11 months.

Nine subjects received a second treatment 30 to 60 days after their first treatment.

Results:

Evaluation Scores before and after Treatment in Patients Who Received One or Two Shockwave Treatments

| | One Treatment | | Two Treatment | |
|--------------------|---------------|-------|---------------|-------|
| | Before | After | Before | After |
| Pain Score | 15.6 | 36.8 | 21.4 | 37.3 |
| Function Score | 13.6 | 28.2 | 18.4 | 28.1 |
| Strength Score | 9.9 | 18.3 | 12.6 | 17.6 |
| Elbow Motion Score | 9.6 | 10.0 | 10.0 | 10.0 |
| Total Score | 39.9 | 93.0 | 50.0 | 90.0 |

Conclusion: The researchers conclude that low energy shockwave treatment seems to be effective for lateral epicondylitis of the elbow in selected patients.

B. Randomized Controlled Trials of ESWT for Lateral Epicondylitis

1. Rompe conducted a randomized, controlled trial to examine the effect of ESWT on chronic tennis elbow. Researchers used the Siemens Osteostar to administer 3 episodes of treatment at a frequency of 3 Hz. Subjects received treatment one time per week for 20 to 30 minutes. (Rompe 1996)

Part 3. ESWT for the Treatment of Lateral Epicondylitis

The active treatment group received 1000 impulses at .08 mJ/mm², and the control group received 10 impulses at .08 mJ/mm². Shockwaves were directed at the anterior aspect of the lateral epicondyle and at 3 points around the site at a radius of 1.5 to 2 cm.

Researchers evaluated patient pain induced by palpating, resisting wrist extension, resisting finger extension, and lifting a chair. A 100-point VAS determined the extent of the pain, grip strength, and pain at night and at rest. Follow-up occurred at 3, 6, and 24 weeks after treatment.

Study Population: Subjects were included in the study if they had pain in the lateral epicondyle for more than 12 months. Subjects must have attempted and failed conservative therapy in the previous 6 months. The study excluded subjects if they experienced shoulder, neck, or thoracic dysfunction, radial nerve entrapment, or reduced range of movement at the elbow. Researchers also prohibited subjects from seeking treatment for the 6 weeks prior to or during ESWT.

The 50 subjects of the treatment group had an average age of 43.9 years and a mean duration of pain of 24.8 months. The 50 placebo subjects had an average age of 41.9 years and a mean duration of pain of 21.9 months.

Results: The treatment group showed significant decreases in pain and increases in grip strength compared to the placebo group at each follow-up.

Number of Subjects by Outcome at 24-week Follow-up

| | Active Treatment Group | Placebo Group |
|----------------------------|------------------------|---------------|
| Excellent and Good Results | 24 | 3 |
| Treatment Failure | 5 | 35 |

2. Using the Storz Minilith, Crowther's prospective, randomized study compared ESWT to steroid injections for patients with tennis elbow. Subjects received 2000 shockwaves for a maximum EFD of 0.1 mJ/mm². Follow-up occurred at 6 weeks and 3 months. (Crowther 2002)

Study Population: Patients were included in the study if they had a history of tennis elbow for longer than 4 months and had not undergone surgical intervention or injection in the previous year. Subjects must also have experienced tenderness over the lateral epicondyle of the humerus and reproducible pain with resisted finger and wrist extension. Subjects were excluded if they experienced shoulder, neck, or thoracic dysfunction, nerve entrapment, a clotting disorder, or anticoagulant therapy.

After 3 subjects withdrew, 48 subjects remained in the ESWT group. Of the 42 subjects randomized to receive injections, 17 refused resulting in 25 subjects in the injection group. The mean age for all subjects was 49 years (range 27 to 69 years).

Results:

Part 3. ESWT for the Treatment of Lateral Epicondylitis

Average VAS scores by Therapy Group at Follow-up

| Therapy Group | Pre-Treatment | 6 weeks | 3 months |
|-----------------|---------------|---------|----------|
| Injection Group | 67 | 21 | 12 |
| ESWT Group | 61 | 35 | 31 |

Twenty-one subjects (84%) in the injection group had a reduction of pain of 50% or more compared with 29 (60%) ESWT subjects.

At 3 months, 10 of the 19 ESWT failures and 2 of the 4 injection failures were referred for surgical release.

Conclusion: The authors conclude that although injections and ESWT relieve symptoms, steroid injections and local anesthetic more effectively treat lateral epicondylitis compared to ESWT.

3. Speed conducted a double-blind randomized controlled trial examining the effect of ESWT on lateral epicondylitis. (Speed 2002)

Subjects received either active ESWT with 1500 pulses at 0.18 mJ/mm² or sham treatment with the Siemens Sonocur device. The placebo group received 0.04 mJ/mm², but the technician avoided the region of interest. Treatments were administered at monthly intervals.

Researchers defined a positive response as 50% improvement from baseline at 3-month follow-up.

Study Population: The researchers included subjects with lateral epicondylitis for at least 3 months. Subjects had tenderness at the common extensor tendon insertions at the lateral epicondyle and pain with resisted extension of the middle finger. The study excluded patients due to anticoagulant therapy, treatment to the area in the previous 6 weeks, or diabetes.

The 40 subjects in the active treatment group had an average age of 46.5 years and an average duration of symptoms of 15.9 months. The 35 subjects in the placebo group had an average age of 48.2 years and an average duration of symptoms of 12 months.

Results: At 3 months, 14 (35%) subjects of the active group and 12 (34%) placebo subjects showed a positive response. No significant differences existed in the degree of change in pain scores.

Average VAS Pain Scores by Treatment Group and Follow-up

| | Baseline | One Month | Two Months | Three Months |
|---------|----------|-----------|------------|--------------|
| ESWT | 73.4 | 65.9 | 54.7 | 47.9 |
| Placebo | 67.2 | 61.1 | 54.3 | 51.5 |

Conclusion: The researchers state that a significant placebo effect occurs in subjects with lateral epicondylitis after moderate doses of ESWT. They continue by stating that “there is no evidence of added benefit of treatment when compared to sham therapy.”

4. Haake studied the effect of ESWT or placebo on lateral epicondylitis in a double-blind, randomized, placebo-controlled study.⁵ (Haake 2002a)

Researchers used low-energy lithotripters to administer the shockwaves. Subjects in the active therapy group received 3 sessions of low-energy ESWT. Researchers applied 2000 pulses using an EFD between 0.07 and 0.09 mJ/mm².

The primary end-point examined success rate at 12-week follow-up. A Roles and Maudsley Pain Score of 1 or 2 defined success. In addition, a successful patient did not receive additional treatment during follow-up.

Study Population: The study included patients with epicondylitis of the radial humerus unresponsive to 6 months of conservative therapy. The subjects failed at least three local injections, at least 10 individual treatments with physiotherapy, and at least 10 individual treatments of physical therapy. Two weeks must have elapsed since the last conservative therapy session. Subjects were excluded due to elbow surgery, thrombopathy, anticoagulant therapy, or hyperthyroidosis.

The active ESWT treatment group included 135 subjects with an average age of 46.9 years. Their symptoms lasted an average of 27.6 months, and they attempted conservative treatment for an average of 22.3 months. The placebo group included 137 subjects with an average age of 46.3 years. The placebo group’s symptoms lasted an average of 22.8 months, and they attempted conservative treatment for an average of 20.2 months.

Results: Researchers withdrew 11 subjects from the active group and 15 subjects from the placebo group due to missing data.

Number of Subjects by Outcome and Treatment Group at 12-Week Follow-up

| | ESWT | Placebo |
|---------|------------|------------|
| Success | 32 (25.8%) | 31 (25.4%) |
| Failure | | |

⁵ Haake used the same study to report the side effects and complications from ESWT or placebo in a separate publication. The ESWT group had a higher likelihood of experiencing side effects compared to the placebo group (OR = 4.3, CI = 2.9 - 6.3). The most frequently reported side effects included reddening of the skin, pain, petechiae, bleeding, and hematoma. Patients who underwent treatment with the Storz Minilith experienced reddening of the skin more frequently than other devices. The Dornier products caused more swelling, petechiae, bleeding, and hematomas. Four patients experienced migraines after treatment with the Siemens Sonocur. (Haake 2002b)

| | | |
|--|------------|------------|
| Total | 92 (74.2%) | 91 (74.6%) |
| Due to additional treatment | 10 (8.1%) | 10 (8.2%) |
| Due to Roles and Maudsley score of 3 or 4 | 53 (42.7%) | 44 (36.1%) |
| Due to additional treatment and Roles and Maudsley score of 3 or 4 | 29 (23.4%) | 37 (30.3%) |
| Total | 124 (100%) | 122 (100%) |

Conclusion: The authors conclude that ESWT in the study was ineffective in the treatment of lateral epicondylitis. They do not recommend that ESWT be used to treat patients with chronic lateral epicondylitis, except in controlled clinical trials.

C. Meta-Evaluations of ESWT for Lateral Epicondylitis.

1. Two independent reviewers assessed randomized and pseudo-randomized trials that compared the use of ESWT as a treatment strategy for individuals with lateral elbow pain. (Buchbinder 2002)

Buchbinder's review included trials that did not conceal treatment or control group allocation from the outcome assessor. A sensitivity analysis including and excluding blinded trials was conducted to test the effect of inclusion of these trials. Studies in all languages were translated into English and considered for inclusion in the review. A sensitivity analysis including and excluding foreign language trials was conducted to test the effect of inclusion of these trials.

The review included two trials that compared ESWT to placebo. The frequency of ESWT application, dosage, and technique were similar in both studies. Both trials also included similar adult study populations with chronic symptoms who had failed conservative treatment.

Results: The first trial conducted by Rompe demonstrated highly significant differences in favor of ESWT whereas the second trial conducted by Haake found no benefits of ESWT over placebo.

After pooling the data from the two trials, the benefits observed in the first trial no longer reached statistical significance. The relative risk for treatment failure (defined as Roles-Maudsley score of 4) of ESWT over placebo was .40 at 6-weeks and .44 at 1-year. After 6 weeks, there was no statistically significant improvement in pain at rest, pain with resisted wrist extension, or pain with resisted middle finger extension. Results after 12 or 24 weeks were similar.

Conclusion: The authors state that they cannot draw definite conclusions about the value of ESWT for chronic lateral elbow pain due to the small number of trials and the trials' conflicting results.

III. Costs

An orthopedic clinic in Seattle, WA intends to charge \$900 per low-energy treatment session. Each treatment requires use of a treatment room for one and a half hours including preparation and clean-up.

Crowther reports that one course of ESWT costs about 300 pounds and the components of an injection amount to 3 pounds. (Crowther 2002)

IV. Department Issues

In 2002, the Department of Labor and Industries accepted 2,494 claims under the International Classification of Diseases code 726.32, lateral epicondylitis.

Top 18 Treatments for Lateral Epicondylitis Claims Paid by LNI, 2002

| Number of Paid Requests | CPT or HCPCS Code | Therapy |
|----------------------------|-----------------------------------|---|
| 98 | 24356 | fasciotomy, lateral or medial |
| 198 | 20550 | injection, tendon sheath, ligament |
| 203 | J8499 | oral prescription drug, NOS |
| 251 | 97112 | neuromuscular reeducation of movement, balance, coordination... |
| 328 | 73070, 73080 | radiologic exam |
| 335 | 97535, 97537 | self-care/home management, community/work reintegration |
| 353 | 20605 | arthrocentesis, aspiration and/or injection, intermediate joint or bursa |
| 354 | 97124 | massage |
| 408 | 97003, 97004 | occupational therapy |
| 427 | 97022 | whirlpool |
| 638 | 97001, 97002 | physical therapy |
| 682 | L3700, L3999, L3908 | upper limb, elbow, wrist orthosis |
| | J2000, J3301, J1030, J1040, J0702 | injection (lidocaine, triamcinolone acetonide, methylprednisolone acetate, methylprednisolone acetate, or betamethasone acetate and betamethasone sodium phosphate) |
| 703 | | therapeutic activities, use of dynamic activities to improve functional performance |
| 1768 | 97530 | electrical stimulation |
| 2975 | 97014, 27032 | ultrasound stimulation |
| 3772 | 97035 | manual therapy techniques (mobilization, manipulation, manual traction) |
| 5668 | 97140 | therapeutic procedures to develop strength and endurance, ROM, flexibility |
| 6481 | 97110 | |

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Part 4. ESWT for the Treatment of Tendinitis of the Shoulder

According to Bosworth's observations of 12,122 shoulders, tendinitis symptoms arise if calcification exceeds 1.5 cm diameter. The disease is often described as self-limiting because over 90% of calcific tendinitis cases respond to conservative therapy. (Spindler 1998) (Daecke 2002)

I. Evidence

The majority of the studies excluded subjects due to neurological disorders, rotator cuff tears, arthritis, tumors, infections, or bursitis of the shoulder.

A. Case Studies of ESWT on Tendinitis of the Shoulder

1. Spindler reports the results of ESWT on 3 female patients with calcific tendinitis of the rotator cuff. The patients had deposits ranging in size from 22 to 31 mm. All had attempted anti-inflammatory drugs and steroid injections for at least one year. (Spindler 1998)

The Dornier Lithotripter administered in one session 4000 pulses averaging 100 beats per minute. Generator energy ranged from 14 to 17 kV.

After 24 hours, the calcium deposits had completely fragmented. After 7 days, the deposits had disappeared. At 2-year follow-up, the 3 patients experienced no symptoms or calcification.

B. Case Series Studies of ESWT on Tendinitis of the Shoulder

1. The prospective pilot study examined the clinical and radiologic effects of high energy ESWT on calcification of the rotator cuff.

Therapy began with low-energy pulses (14 kV) that constantly increased up to 22 kV. Researchers applied 2000 pulses to all patients. Subjects underwent a second ESWT session 2 weeks later. (Loew 1995)

Pain, activity, active pain-free motion, and strength were measured with the 100-point Constant functional score. Follow-up occurred at 6 and 12-week follow-up.

Study Population: The study included subjects if they had a history of symptoms for a minimum of 12 months. They also had radiologically confirmed calcification of the rotator cuff with a diameter greater than 10 mm and defined as Type I on the DePalma classification. Magnetic resonance imaging (MRI) showed the calcification in the supraspinatus tendon. In addition, the subjects failed 12 months of conservative treatment and stopped the treatments 3 months prior to ESWT.

The average age of the 20 patients was 50 years (range 35 to 72 years). Their duration of symptoms averaged 34 months, and calcium deposits were present for an average of 18 months.

Results: The average Constant score before the study was 43 (range 18 to 64). After 2 weeks, 11 subjects reported subjective improvement in pain-free motion and pain while at rest. The calcium deposits had begun to disintegrate in 4 subjects.

At 6 weeks, the median score for all subjects equaled 63 points. Twelve patients' scores improved by at least 20 points on the 100-point scale. Five patients showed no change. The calcium deposits disappeared in 4 subjects.

At 12 weeks, the patients' median score equaled 69 points. Fifteen patients experienced an improvement in their symptoms. Seven subjects' deposits disappeared.

Treatment caused subcutaneous hematomas in 14 patients and osseous edema in one patient.

2. The prospective study followed subjects for one month using a 10-point VAS. (Pigozzi 2000)

Patients received 0.03 to 0.50 mJ/mm² at 60 to 240 beats per minute. On average, researchers used 2000 beats with a frequency of 240 impulses per minute at a level of 0.21 mJ/mm². Patients underwent one treatment per week for 8 weeks.

Study Population: The study included patients with symptoms for at least 2 months and unresponsive to physiotherapy. Patients could not have undergone treatment 5 weeks before, during, or following the trial.

The 72 patients had an average age of 38 years (range 18 to 69 years). In 34 cases, the patients had failed one or more local infiltrations with corticosteroid. Calcium deposits were detected in 19 subjects.

Results:

Number of Subjects by Rating One Months after ESWT

| Rating | Definition | Number of Subjects (%) |
|-----------|---|------------------------|
| Excellent | no pain, full movement, and felt satisfied with treatment outcomes | 38 (52.7%) |
| Good | less pronounced pain, full movement, and satisfaction with treatment outcomes | 10 (13.8%) |
| Fair | more tolerable pain and slight satisfaction with treatment outcomes | 9 (12.5%) |
| Poor | persistent or more pronounced symptoms | 15 (20.9%) |

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Seven cases (37%) experienced a reduction or fragmentation of the deposit while 12 (63%) did not show any changes radiologically.

Of the 24 patients who did not have satisfactory results, 15 (62.5%) subjects did not report any improvement after 4 sessions.

Conclusion: The authors suggest that deciding whether or not to interrupt treatment may occur after the first 4 applications.

3. Researchers prospectively monitored subjects who underwent 2 or 3 treatments with a Dornier device. An average of 13.4 days elapsed between the sessions. The 2000 impulses provided an average cumulative dose of 1300 mJ/mm² over 2 to 3 sessions. Researchers used ultrasound to determine the treatment area. (Charrin 2001)

Researchers used subjective results, a VAS, the Constant score, and the Association of Shoulder and Elbow Surgeons' (ASES) questionnaire to assess patients at 3, 6, 12, and 24-week follow-up.

Study Population: The study included patients with rotator cuff calcific tendinitis who experienced pain for at least 6 months. Subjects also had radiological evidence of either a Type A (homogeneous and defined) or Type B (heterogeneous, multilobulated or fragmented, and sharply defined) calcific deposit at least 10 mm in length. Patients were excluded due to cervical abnormality, adhesive capsulitis, glucocorticoid injection within 6 weeks prior to ESWT, or anticoagulant therapy.

The study's 32 patients had an average age of 49.8 years and symptom duration of 52.1 months.

Results: Patient VAS scores improved through 24 weeks while ASES and Constant scores improved through 12 weeks.

| Number of Subjects by Assessment and Follow-up | | | | |
|--|---------|---------|----------|----------|
| Assessment | 3 weeks | 6 weeks | 12 weeks | 24 weeks |
| subjective improvement | 16 | 12 | 11 | 16 |
| deposit no longer visible | 2 | 2 | 0 | 5 |

The authors found a subjective clinical improvement in 36.6% of patients after 12-weeks and 55.1% of patients at 24-weeks. The study also noted clearance of deposits in 6.6% and 17.2% of cases.

Some patients experienced superficial hematomas after the sessions.

Conclusion: The outcomes after ESWT were less favorable than other studies of ESWT and studies of conventional therapies.

C. Studies with Comparison Groups Examining ESWT on Tendinitis of the Shoulder

1. Loew compared different methods of ESWT application in the treatment of chronic and symptomatic calcified lesions. (Loew 1999)

Researchers used the Philips electrohydraulic lithotripter. Researchers divided the 80 patients into groups of 20 and followed the 4 groups for 3 months. One week elapsed between treatments.

Group 0 acted as the placebo group and received no treatment.

Group 1 received a single 2000 impulse, low-energy treatment (EFD 0.1 mJ/mm²).

Group 2 received a single 2000 impulse, high-energy treatment (EFD 0.3 mJ/mm²).

Group 3 received two 2000 impulse, high-energy treatments (EFD 0.3 mJ/mm²).

The assessment included patient opinion, radiological changes, and a functional exam. Complete disappearance of the deposit or obvious resorption defined an effective treatment. The study also evaluated function by comparing Constant and Murley scores before and after treatment.

Study Population: The study included patients whose shoulder pain lasted at least 12 months despite attempts at physiotherapy and subacromial injections of steroid. Radiological imaging confirmed that the diameter of the calcifications spanned at least 1.5 cm. The deposits also showed signs of disintegration or resorption and were classified as Gartner Type I or II.

Results:

Clinical Results at 3-Month Follow-up after Electrohydraulic ESWT by Group

| | Group 0A: control | Group 1A: low energy | Group 2A: high energy, one session | Group 3A: high energy, 2 sessions |
|-------------------------|----------------------|----------------------------|--|---|
| Average Constant Scores | | | | |
| Before Treatment | 44.5 | 39.4 | 39.0 | 43.5 |
| 3-month follow-up | 47.8 | 51.6 | 63.7 | 68.5 |
| Number of Subjects | | | | |
| Disintegrated Deposits | 2 | 4 | 11 | 12 |

Conclusion: The authors state that high-energy ESWT should be considered before surgery for chronic calcific tendinitis in patients after a minimum of 6 months on non-invasive treatment, with deposits greater than 1.5 cm and no radiological evidence of spontaneous disintegration.

2. The prospective placebo-controlled, single-blind pilot studied the effects of low-energy ESWT on function and pain in tendinitis of the supraspinatus without calcification. Researchers practiced intention to treat. (Schmitt 2001)

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Patients were randomized through permuted blocks into either an active treatment or placebo group. The treatment group received 6000 impulses (EFD 0.1mJ/mm²) in 3 sessions at intervals of one week. The placebo group received 6000 impulses of sham ESWT.

An observer followed subjects at 6 and 12-weeks by evaluating Constant scores and a 10-point VAS. Researchers defined success as an increase in the Constant score of at least 30 points or an absolute score of 80% of the normal value.

Study Population: The study included patients with chronic tendinitis without calcification whose symptoms lasted 6 months. Subjects had free range of motion and free rotation. They must have failed 10 sessions of physiotherapy and 2 subacromial injections. In addition, patients did not attempt treatment in the 4 weeks prior to ESWT. Subjects were excluded if they had previous shoulder operations.

The 20 active treatment patients and the 20 control patients had a mean age of 52 years.

Results: At 6 and 12-weeks, 19 of the treatment group and 18 of the control group returned for follow-up.

| Parameter | Control | Treatment |
|-------------------------------------|---------|-----------|
| Constant score | | |
| pretreatment | 42.2 | 40.7 |
| 6 weeks | 64.2 | 61.0 |
| 12 weeks | 64.4 | 66.5 |
| Pain during activity (10 point VAS) | | |
| pretreatment | 8.0 | 7.8 |
| 6 weeks | 5.7 | 5.7 |
| 12 weeks | 6.1 | 4.9 |
| Number of Successful Treatments | 8 | 10 |
| Subjective Improvement (%) | | |
| 6 weeks | 26.3 | 28.4 |
| 12 weeks | 31.1 | 40.0 |

Researchers did not detect statistically significant results at 6 or 12-week follow-up.

Conclusion: The authors state that the use of low-energy ESWT in the treatment of tendinitis of the supraspinatus is time-consuming, expensive, and probably ineffective compared with subacromial injections.

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3. Haake conducted a prospective, blinded, randomized 2-sample parallel group study. Blinded, independent observers assessed Constant and Murley scores at 12-weeks and one-year. Researchers practiced intention to treat. (Haake 2002)

Group 1 received 4000 impulses (EFD 0.78 mJ/mm²) in two treatment sessions. ESWT was aimed at the origin of the supraspinatus tendon.

Group 2 received 4000 impulses (EFD 0.78 mJ/mm²) in two treatment sessions. ESWT was aimed at the calcified area.

Study Population: The study included patients with calcifying tendinopathy, Gartner Stage I or II of at least .5 cm diameter. Patients experienced symptoms for at least 6 months, but had free range of motion. In addition, they failed 10 physiotherapy sessions, 2 subacromial injections, and 6 sessions of physical therapy with NSAIDs. The treatments must have occurred more than 4 weeks before starting ESWT. Patients were excluded if they had previous surgery to the shoulder.

The 50 patients had an average age of 50 years (range 29 to 68 years). The two groups each included 25 subjects.

Results: At 1-year follow-up, all 25 patients in the calcific deposit group felt satisfied with their treatment results, whereas 11 subjects in the tuberculum majus group felt satisfied. For patients in the tuberculum majus group, improvement in the Constant and Murley score and pain score was comparable to the natural history of the disease.

Clinical Results by Parameter, Group, and Follow-up

| Parameter | Focus on Deposit | Focus on Tuberculum Majus |
|---------------------------------|------------------|------------------------------|
| Constant and Murley scores | | |
| Before Intervention | 50.0 | 47.2 |
| 12 weeks | 104.6 | 73.1 |
| 1 year | 116.2 | 83.5 |
| Number of successful treatments | | |
| 12 weeks | 20 | 7 |
| 1 year | 25 | 10 |
| Subjective improvement (%) | | |
| 12 weeks | 57.5 | 31.7 |
| 1 year | 81.4 | 47.0 |

2x2 Cross Table for Complete Resorption of the Calcific Deposit 1 year after ESWT

| Group | Resorption | No resorption | Number |
|--------|------------|---------------|--------|
| CD | 14 | 10 | 24 |
| TM | 8 | 14 | 22 |
| Number | 22 | 24 | 46 |

The researchers did not find significant differences in resorption rates between the 2 groups.

Conclusion: The study suggests that 2 sessions of ESWT at 2000 impulses with an EFD of 0.78 mJ/mm² effectively treats calcifying tendinopathy of the supraspinatus muscle when it is focused at the calcific deposit.

4. Speed compared the effect of ESWT to a sham treatment in addressing tendinitis of the rotator cuff. (Speed 2002)

The Sonocur device generated waves from an electromagnetic generator. Patients received 3 treatments at monthly intervals. The active treatment group received 1500 pulses at 0.12 mJ/mm² while the control group received 0.04 mJ/mm².

Speed measured pain and disability related to preceding week with the Shoulder Pain and Disability Index (SPADI). The study also included a 100-point VAS. Follow-up occurred at 1 and 4-months. Patients could not seek other treatment during the study.

Plain radiographs and ultrasound revealed no evidence of calcification before treatment. Researchers used ultrasound to determine the area requiring treatment.

Study Population: The study included patients with pain in the shoulder for at least 3 months with clinical signs of a unilateral tendinitis of the rotator cuff. They experienced pain without weakness on resisted testing of one or more musculotendinous units of the rotator cuff. Patients were excluded if they had a coagulation disorder, diabetes, or vasculitis. Undergoing treatment within the previous 6 weeks also excluded patients.

Results: At 3 months, 12 (35%) of the ESWT group and 18 (45%) in the sham group showed a positive response of 50% improvement on the SPADI. Both groups showed significant and sustained improvements beginning at two months. No significant difference between the groups in the degree of change on the SPADI occurred during the 6-month period.

Conclusion: The authors note a significant and sustained placebo effect after a moderate dose of ESWT. Active ESWT compared to sham treatment does not provide added benefit.

5. Daecke compared different methods of ESWT application in the treatment of chronic and symptomatic calcified lesions.⁶ (Daecke 2002)

The study used the Dornier electromagnetic lithotripter. Researchers divided the 115 patients into 2 groups. One week elapsed between treatments. Group A included 56 patients treated with a single 2000 impulse, high-energy treatment (EFD 0.3 mJ/mm²).

⁶ Loew previously reported the short-term results of this study in 1999. (Loew 1999)

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Group B included 59 subjects who received two 2000 impulse, high-energy treatments (EFD 0.3 mJ/mm²).

The assessment included patient opinion, radiological changes, and a functional exam with follow-up at 3 and 6 months and 4 years. Complete disappearance of the deposit or obvious resorption defined an effective treatment. Researchers also compared pre and post-treatment Constant and Murley scores.

Study Population: The study included patients whose shoulder pain lasted at least 12 months despite attempts at physiotherapy and subacromial injections of steroid. Radiological imaging confirmed that the diameter of the calcifications spanned at least 1.5 cm. The deposits also showed signs of disintegration or resorption and were classified as Gartner Type I or II.

The 115 patients had a mean age of 49 years (range 28 to 77 years). The mean duration of symptoms equaled 5 years.

Results: The follow-up rate was 87% at 3 months, 72% at 6 months, and 92% at 4 years.

73% of Group A (high energy, one session) and 63% of Group B (high energy, two sessions) received additional therapy between 6-month and 4-year follow-up. In addition, 23 patients (25% in Group A and 19% in Group B) underwent surgery after ESWT.

Clinical Results at 6-Month Follow-up after Electromagnetic ESWT by Group

| Parameter | Group A: high energy, one session | Group B: high energy, two sessions |
|---|-----------------------------------|------------------------------------|
| Average Constant Scores | | |
| Before Treatment | 49 | 44 |
| 3-month | 62 | 62 |
| 6-month | 67 | 69 |
| 4 year | 88 | 85 |
| % of Subjects with Partial or Complete Calcification Resorption | | |
| 3-month | 30% | 52% |
| 6-month | 47% | 77% |
| 4 year | 93% | 93% |

Conclusion: The authors state that the study confirms the effectiveness of ESWT in calcific tendinitis of the shoulder and demonstrates that the results are dose-dependent. In addition, ESWT should only be performed when a conservative approach to pain associated with a dense and demarcated calcific deposit has failed.

D. Cost-Effectiveness Studies of ESWT on Tendinitis

1. Haake examined the cost-effectiveness of ESWT compared to surgery in treating tendinitis. The study group consisted of 60 patients with clinical evidence of chronic tendinitis of the supraspinatus muscle, some with calcifying tendinitis. (Haake 2001)

Subjects with calcifying tendinitis underwent 2 ESWT treatments administered one week apart with 2000 impulses (EFD 0.35 mJ/mm²). Subjects with supraspinatus tendinitis underwent 3 ESWT treatments administered one week apart with 2000 impulses (EFD 0.08 to 0.14 mJ/mm²).

Clinical success depended on the results from the Subjective Shoulder Rating System (SSRS) 12 weeks after operation. Researchers defined success as a score of 80 or less. Researchers also classified subjects as a success if they increased their score at least 30 points following treatment and had a score of 70 or less. An increase of 15 points and a score of 70 or less qualified as satisfactory.

Study Population: The subjects failed conservative treatment for 6 months and had Type 1 or 2 Gaertner calcific deposits with a minimum diameter of 1 cm.

The 30 patients who underwent ESWT had an average age of 49.7 years compared to 51.1 years for the 30 patients who underwent surgery with acromioplasty.

Results: Researchers based costs data on the median value of the actual reimbursed amounts. Outpatient physiotherapy costs equaled the period from first ESWT or from hospital discharge to 12-week follow-up and were based on EUR 12.90 per treatment.

The study also used the following calculation:

Direct hospitalization = Nursing Cost Tariff of Philipps-University * average length of stay

Average Cost and Range Data in Euros

| Cost Category | Surgery | ESWT |
|-----------------------|---------|-------|
| Overall Costs | 22,735 | 3,180 |
| Hospital stay or ESWT | 3,764 | 688 |
| Physiotherapy | 534 | 187 |
| Lost Productivity | 10,000 | 1,190 |

Clinical Classification of Subjects at 12-Week Follow-up

| Clinical Result | Number (%) of Subjects | |
|---------------------------|------------------------|----------|
| | Surgery | ESWT |
| Good or very good results | 17 (57%) | 20 (67%) |
| Satisfactory result | 6 (20%) | 3 (10%) |
| Disintegration of deposit | 25 (83%) | 13 (43%) |

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The average period of lost work following discharge after surgery was 66.9 days as opposed to 7.7 days after ESWT. Patients required an average of 39.3 physiotherapy sessions after surgery compared to 13.9 sessions after ESWT.

II. Department Issues

In 2002, the Department of Labor and Industries accepted 2,977 claims under the International Classification of Diseases code 726.10, tendinitis of the shoulder.

Top 14 Treatments for Shoulder Tendinitis Claims Paid by LNI, 2002

| Number of Paid Requests | CPT or HCPCS Code | Therapy |
|-------------------------------|---|---|
| 4900 | 97110 | therapeutic proc to develop strength and endurance, ROM, flexibility |
| 3554 | 97140 | manual therapy techniques (mobilization, manipulation, manual traction) |
| 2192 | 97014 | electrical stimulation |
| 2128 | 97035 | ultrasound stimulation |
| 1318 | 97530 | therapeutic act, use of dynamic act to improve functional performance |
| | J2000, J3310, J1030, J1040, J0702 | injection (lidocaine, perphenazine, methylprednisolone acetate, or betamethasone acetate and betamethasone sodium phosphate) |
| 696 | 20610 | arthrocentesis, aspiration, and/or injection, major joint |
| 576 | 97001, 97002 | physical therapy |
| 573 | 97535, 97537 | community, work reintegration, self-care, home management |
| 389 | 97112 | neuromuscular re-ed of movement, balance, coordination |
| 377 | 97124 | massage |
| 203 | 29826 | arthroscopy, decompression of subacromial space with partial acromioplasty |
| 181 | 23130 | acromioplasty or acromionectomy |
| 94 | 23120 | claviclectomy, partial |
| 77 | | |

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Part 5. ESWT for the Treatment of Delayed Union Fractures and Nonunions

I. Evidence

The majority of the studies excluded subjects due to coagulation disorders, pregnancy, malignancy, infections, pathological fractures, or defects close to growth plates.

A. Case Studies of ESWT on Delayed Fractures and Nonunions

1. Ikeda reported the results of ESWT on 6 patients with delayed union or nonunion of fractures of the tibiae (3), radius (1), femur (1), and humerus (1). The subjects had an average age of 38.6 years, and the average time from previous surgery to ESWT was 14 months. (Ikeda 1999)

Four of the 6 cases achieved bone union an average of 4.3 months after ESWT. They did not experience complications, except mild subcutaneous hemorrhage. The 2 failures may have resulted from unstable nonunion and avascular nonunion.

Ikeda also details the experiences of 2 male patients. A 30 year-old male had a delayed union of the right tibia. Three months following 130 shots of ESWT, he could walk and a radiogram showed a callus formation. He achieved solid fusion at 7 months. A 23 year-old male subject had a fracture of the left tibia that had not healed in 5 years. Four months following 200 shots of ESWT, radiograms showed evidence of callus bridging, and the subject could run. He achieved solid fusion at 10 months.

Conclusion: The authors conclude that ESWT safely and effectively treats delayed and nonunion if used with care.

B. Case Series Studies of ESWT on Delayed Fractures and Nonunions

1. Valchanou conducted a case series evaluating the effect of high-energy ESWT on the treatment of delayed and nonunion fractures. Patients underwent a single treatment using 1000 to 4000 shockwaves. Most fractures were then immobilized in a plaster cast for an average of 81 days (range 20 to 120 days). (Valchanou 1991)

Study Population: The series monitored 82 delayed fractures or nonunions in 71 men and 8 women. The subjects had an average age of 28 years (range 9 to 76 years), and the average time between injury and treatment was 20.2 months.

Results: Radiological examination showed bony union in 70 (85.4%) of the fractures. The treatment had no effect in 12 fractures, including 1 delayed femur union, 4 scaphoid nonunions, 3 tibia nonunions, 2 radius nonunions, 1 ulna nonunion, and 1 patella nonunion.

Conclusion: The authors conclude that high-energy shockwaves may usefully treat delayed and nonunions.

2. Vogel evaluated the effect of ESWT on nonunion fractures of bones of the lower extremity. (Vogel 1997)

The Siemens Osteostar electromagnetic shock-wave generator provided 3000 impulses with an EFD of 0.6 mJ/mm². Researchers targeted the pseudoarthrotic gap and the adjacent cortical structures. The single treatment session lasted from 35 to 65 minutes.

Follow-up occurred at 3, 6, 12, 18, 24, and 52 months.

Study Population: Patients in the study had a nonunion with a history of more than 6 months. Subjects were excluded if they presented with acute osteomyelitis.

The 23 women and 25 men had an average age of 38 years (range 12 to 81 years). The mean duration of nonunion was 12 months, and 73% of the nonunions affected the tibia or femur.

Results: After a mean of 3.4 months, 29 (60.4%) patients showed complete healing of the pseudoarthrosis documented radiologically.

The side effects that patients experienced included petechia, dermal erosion, and local edema.

Conclusion: While surgical therapy still represents the golden standard, the clinical results justify the use of ESWT.

3. Schaden conducted a case series studying ESWT on fractures. Patients underwent one ESWT treatment followed by immobilization with casts or splints. The ESWT treatment lasted 20 to 60 minutes. If the fracture affected the scaphoid, therapy consisted of an EFD of 0.25 to 0.35 mJ/mm² (20-24kV) and 1000 to 2500 shockwaves. If the fracture affected the tibia or femur, therapy consisted of an EFD of 0.4 mJ/mm² (28kV) and 12,000 shockwaves. (Schaden 2001)

Follow-up occurred at 18 months.

Study Population: The study included 41 females and 74 males with nonunion or delayed fractures. Seventy-two fractures affected the shaft of long bones while 43 fractures affected cancellous bones. Subjects were excluded if the epiphyseal plate, brain, spine, or alveolar tissue fell within the shockwave field.

The time from injury or last operation to ESWT for 35 patients was between 3 and 6 months. More than 6 months had passed from injury or last operation to ESWT for

Part 5. ESWT for the Treatment of Delayed Union Fractures and Nonunions

80 patients. Previous operative treatments had failed 92 patients. Sixty patients still had devices present at the time of ESWT.

Results: Of the 115 subjects, 87 (75.7%) patients achieved union. The 28 (24.3%) patients who failed treatment may not have healed because of fracture gaps, defective zones wider than 5 mm, or inadequately immobilized fractures.

Treatment side effects included local hematoma, petechial hemorrhage, and local swelling. However, no hematoma resulted in treatments with EFD below 0.25 mJ/mm² (20kV) and 1500 shockwaves.

Conclusion: The researchers were unable to make a general correlation between ESWT and determination of healing success because of the heterogeneous fracture cases and the small number of patients.

4. Rompe designed a prospective cohort study to examine the effect of high-energy ESWT on bony nonunions of the femur or tibia after fracture or corrective osteotomy. An independent observer made the decision whether bony healing had occurred. (Rompe 2001)

The Siemens Osteostar provided high energy therapy with 3000 impulses and an EFD of 0.6 mJ/mm². Researchers targeted the waves to the gap and to the adjacent cortical structures. Treatment lasted from 50 to 75 minutes.

Follow-up occurred at 8 weeks and monthly until 9 months passed or until the patient achieved bony healing.

Study Population: Subjects received a diagnosis of pseudoarthrosis when a minimum of 9 months had elapsed since the last operation and radiographs did not show bridging of the 4 bone cortices. Patients were excluded if they showed a loosening of screws or plates, a bone gap more than 0.5 cm after surgery, thrombophlebitis, vascular insufficiency, drug addiction, hepatitis, or HIV. They were also excluded if they required steroids, anticoagulants, nonsteroidal anti-inflammatory medications, diphosphonate therapy, calcium channel blockers, or immunosuppressive therapy.

Of the 20 women and 23 men who entered the study, 17 subjects had pseudoarthroses after fracture, and 26 had pseudoarthroses after osteotomies. The subjects failed an average of 1.9 operations.

Results: After an average of 4.0 months, 31 of 43 (72.1%) pseudoarthroses showed bridging of all 4 cortices. Full weight bearing was allowed for these subjects.

Of the 35 subjects with a positive bone scan, 29 (82.9%) showed healing of the pseudoarthrosis compared to the 2 of 8 (25%) subjects with negative bone scans. Six of the 8 smoked heavily.

Part 5. ESWT for the Treatment of Delayed Union Fractures and Nonunions

Half of the 8 tibial and 66% of the 9 femoral post-fracture nonunions achieved success. 72% of the patients showed radiologic success.

Researchers observed better results after postosteotomy than after post-fracture nonunions.

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Part 6. Adverse Events

Common adverse effects after ESWT include:

- pain during treatment
- localized numbness, tingling, or decreased sensation at the site of therapy
- localized subcutaneous hematoma, bruising, or petechial bleeding at the treatment site
- rupture of the plantar fascia
- misdirection of ESWT energy to a major nerve or blood vessel
- anesthesia complications
- nausea
- sweating and dizziness (FDA 2000) (FDA 2002)

Naguib also published a prospective cohort study investigating the effect of extracorporeal shockwave lithotripsy (ESWL) on the hearing of both patients and staff. (Naguib 2002) The study also included a comparison group of healthy subjects not exposed to ESWL.

Results: Transient Evoked Otoacoustic Emissions (TEOAE) values showed significant differences between pre and post-treatment tests. 31 (94%) of single exposure subjects and 12 (100%) multi-exposure subjects had no response at 1, 2, 4, and 6-hour follow-up. After 24 hours, 5 (15.2%) single exposure patients responded compared to 0 (0%) multi-exposure subjects.

Single exposure patients regained response to TEOAE after an average of 53.6 hours compared to 58.91 hours in patients with multiple exposures.

Noise induced by ESWL was within the acceptable limits of industrial noise stimulation. Peak levels were less than the 140 dB peak action level for impulsive or impact noise exposure.

Conclusion: ESWL's potentially hazardous effect on hearing is pre-clinical, detected only by TEOAE, and related to the frequency of exposure. Subjects experienced temporary subjective hearing loss and tinnitus reflecting a temporary biomechanical derangement of the outer hair cells.

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Part 7. Other Payer Systems and Insurers

I. National Payer Systems

An article published in the *International Journal of Technology Assessment in Health Care* summarized the reimbursement approach taken by Germany, Switzerland, and Austria. (Wild 2000)

In 1995, the German Society of Shock Wave Therapy made a consensus statement that ESWT may be used to treat tendinosis calcarea, calcaneal spur, epicondylitis humeri radialis, and pseudoarthrosis. After Germany's compulsory health insurers received 40,000 applications for ESWT in 1996 representing DM 30 million (15 million Euro), the national insurers chose to reevaluate ESWT. The German Systematic Review indicated that ESWT tends toward therapeutic effect, but that the publications did not adequately demonstrate efficacy or effectiveness. Furthermore, the review stated that ESWT had not advanced past an experimental stage. The conclusion that "neither the benefit, nor the medical necessity, nor the efficiency" of ESWT had been proven led to suspension of reimbursement for the four indications. This decision was confirmed in an appeal to the court in early 1999.

Switzerland's Commission of Health Insurers also concluded in May 1998 in a unanimous resolution not to include ESWT in their cost catalog.

In contrast, Austria decided in 1999 that insurers would reimburse ESWT for a maximum of two sessions per patient at certain medical centers. In addition, the Ministry of Health decided neither to reward ESWT with additional points in the DRG system in hospitals nor to support the purchase of lithotripters.

II. Medicare

While the Centers for Medicare and Medicaid Services (CMS) has not made a national coverage policy regarding ESWT, Georgia's local Part B carrier has decided to cover low-energy ESWT. Their policy, which will become effective in April 2003, covers ESWT for plantar fasciitis and lateral epicondylitis.

Medicare Part B in Georgia will cover ESWT utilizing the Dornier Epos Ultra device for the treatment of chronic plantar fasciitis. Patients must meet the following criteria:

- have experienced pain from plantar fasciitis for at least 6 months that has not responded sufficiently to conservative measures (e.g. rest, physical therapy, or medications).
- have undergone an appropriate imaging study to rule out other underlying pathology (e.g., malignancy or fracture).

Medicare will limit coverage to a single session for the treatment of plantar fasciitis.

Part 7. Other Payer Systems and Insurers

Medicare Part B in Georgia will cover ESWT utilizing the Sonocur Basic device for the treatment of chronic lateral epicondylitis (chronic tennis elbow). Patients must meet all of the following criteria:

- have a localized, palpable area of tenderness on physical exam consistent with a diagnosis of lateral epicondylitis.
- have had symptoms for at least 6 months despite conservative therapy.
- have undergone an appropriate imaging study (x-ray, CT scan, MRI, etc.) prior to Sonocur treatment in order to rule out other underlying pathology (e.g., malignancy or fracture).

Medicare in Georgia will not cover ESWT for lateral epicondylitis if the patient has:

- Poorly localized or non-palpable area of pain
- Pregnancy
- A bleeding disorder such as hemophilia or an acquired bleeding disorder (Patients on Coumadin (Warfarin) or other anti-coagulants should discontinue their medication prior to treatment, and patients taking aspirin or other NSAIDs should discontinue these medication one week prior to treatment.
- Blood dyscrasia or other disorder with platelet count less than 50,000
- An open wound over the site to be treated
- Redness, swelling, fever, infection, or acute inflammation at the site to be treated
- Inability to cooperate and follow directions

Medicare will limit coverage to a total three sessions for the treatment of lateral epicondylitis. (Georgia 2002)

III. Blue Cross Blue Shield Carriers

The March 2002 policy from Blue Cross Blue Shield of California states that ESWT is considered investigational/not medically necessary for:

- plantar fasciitis
- epicondylitis (i.e., tennis elbow)
- tendinopathies including calcific tendinitis of the shoulder
- stress fracture, delayed union, nonunion, and
- avascular necrosis of the femoral head (WellPoint 2002)

In July 2002, Wellmark Blue Cross Blue Shield of Iowa and South Dakota determined that ESWT might be considered medically necessary for the treatment of chronic proximal plantar fasciitis as an alternate to surgical therapy on prior approvals. Patients must meet the following:

- symptoms persist for at least 6 months
- lack of response to at least 3 other conservative treatment such as rest, physical therapy, anti-inflammatory medications, local corticosteroids, heel orthotics

However, Wellmark considers ESWT as investigational for the treatment of epicondylitis, tendinopathies, stress fracture, delayed union and nonunion fractures, and avascular necrosis of the femoral head. (Wellmark 2002)

In March 2002, Regence Group of Idaho, Oregon, Utah, and Washington stated that ESWT may be considered medically necessary for the treatment of patients with chronic plantar fasciitis as an alternative to surgical therapy when:

- symptoms persist for at least 6 months
- lack of response to at least 3 other conservative treatment such as rest, physical therapy, anti-inflammatory medications, local corticosteroids, heel orthotics

The policy also states that if the patient does not respond to initial treatment after 12 weeks, a second treatment may be considered medically necessary. However, more is considered investigational.

Regence considers ESWT as investigational for the treatment of epicondylitis, tendinopathies, stress fracture, delayed union and nonunion fractures, and avascular necrosis of the femoral head. (Regence 2002)

IV. Private Insurers

Aetna's September 2002 policy states that Aetna does not cover ESWT for plantar fasciitis, as it is considered experimental and investigational for this indication. Aetna also does not cover ESWT for epicondylitis because there is insufficient evidence of effectiveness of ESWT for this indication in the medical literature. (Aetna 2002)

As of June 2002, Humana members were not eligible under the plan for ESWT for plantar fasciitis. Humana's policy states that the technology is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language. (Humana 2002)

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Part 8. Conclusion

Research of extracorporeal shockwave therapy has examined its effect on chronic plantar fasciitis, lateral epicondylitis, tendonitis of the shoulder, and fracture nonunions. However, the exact mechanism of action for these musculoskeletal conditions remains unknown.

Therapy protocols and exact patient inclusion criteria are not uniform between studies. While the results from many of the studies suggest that ESWT may provide relief from pain, a substantial proportion of placebo subjects from randomized controlled trials also experienced clinical improvement. Therefore, the evidence establishing effectiveness for musculoskeletal indications remains inconclusive.